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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/537,416	03/29/2000	Yoshiki Takashima	Q58481	6832
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Sughrue Mion Zinn MacPeak & Seas PLLC 2100 Pennsylvania Avenue N W Washington, DC 20037-3213			EXAMINER	
			MARX, IRENE	
			ART UNIT	PAPER NUMBER
			1651	12
			DATE MAILED: 12/19/2002	

Please find below and/or attached an Office communication concerning this application or proceeding.

## Application No.

09/537,416

Applicant(s)

Examiner

Office Action Summary

Art Unit

1651

Takashima et al.



Irene Marx -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on *Oct 25, 2002* 2b) This action is non-final. 2a) X This action is FINAL. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213. Disposition of Claims is/are pending in the application. 4) X Claim(s) 2-4 and 9-22 4a) Of the above, claim(s) \_\_\_\_\_\_ is/are withdrawn from consideration. is/are allowed. 5) Claim(s) 6) X Claim(s) 2-4 and 9-22 is/are rejected. is/are objected to. 7) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. 8) Claims **Application Papers** 9) The specification is objected to by the Examiner. is/are a)  $\square$  accepted or b)  $\square$  objected to by the Examiner. 10) The drawing(s) filed on Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action. 12) The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. §§ 119 and 120 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) ☐ All b) ☐ Some\* c) ☐ None of: 1.  $\square$  Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \*See the attached detailed Office action for a list of the certified copies not received. 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) L The translation of the foreign language provisional application has been received. 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. 4) Interview Summary (PTO-413) Paper No(s). 1) Notice of References Cited (PTO-892) 5) Notice of Informal Patent Application (PTO-152) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s).

6) Other:

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#### **DETAILED ACTION**

The amendment filed 10/25/02 is acknowledged. Claims 2-4 and 9-22 are pending and are considered on the merits.

Applicant is cautioned that amended claims 10-18 were improperly indicated as "new" rather than "amended".

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112: The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-4 and 9-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At least claims 10, 11, 12, 16, and 17 remain confusing in that the nature of "an optical isomer II" is not clearly defined. Is "the isomer" intended?

The claims are vague indefinite and confusing in that it is unclear what is intended to be encompassed by "reacting a biological material which has **an** ability of converting". The nature of the "biological activity" is not identified and it is unclear what constitutes "an ability" in this context. It is "the" ability?

The claims fail to find proper antecedent basis for "said optical isomer I". The isomer appears to be designated "1". The claims remain confusing because of the inconsistent recitation "(1)" and (I).

The process of claim 18 remains confusing in lacking a recovery step and in that the nature of the process remains unclear. The claim is rendered indefinite by the use of a word of degree such as "increased" as a limitation, i.e., the extent and manner of increase in the optical purity in this process is not set forth with sufficient particularity..

Claims 13-15 remain vague, indefinite and confusing in that the nature of the "improved" optical purity cannot be determined.

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When words of degree, such as "increased" or "improved" are used as a limitation, it is necessary to determine whether the specification provides some standard for measuring that degree. See *Seattle Box Company, Inc. V. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984). In this case, the specification does not enable one skilled in the art to reasonably establish what may be construed as being within the metes and bounds of the word of degree. Therefore, one of ordinary skill in the art would not be apprised as to the claimed invention's scope when the claims are read in light of the specification. See *Ex parte Oetiker*, 23 USPQ2d 1641. In addition, the claims do not set forth with any particularity whether or not an enantiomer is produced. The product is not recovered.

In claims 13-15 the antecedent basis of the phrase "wherein the mixture is not a racemic mixture" is unclear. Is it the original mixture or the mixture produced?

## Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive. For example, the discussion of "(1)" v. "(I)" is noted. However, the correction is incomplete. With respect to definitions for "improved" or "increased", the extent of the improvement or increase in claims 13-15 and 18 for example, is uncertain. The discussion at pages 11-12 of the Response does not provide the necessary clarification. At page 16, lines 3-8 of the specification there is no clear definition of the intended meaning of the terms of degree criticized.

Therefore the rejections are deemed proper and it is adhered to.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final

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action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is before final (703) 872-9306 and after final, (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235. Yeur wark Irene Marx

**Primary Examiner** 

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